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In re application of	Before the Board of Appeals
MIZOBUCHI, Noriko et al.	Appeal No.:
Appl. No.: 09/242,700	Group: 1616
Filed: April 19, 1999	Examiner: GOLLAMUDI, S.S.
Conf.: 1380	
For: A STABLE OINTMENT CONTAINING ASPIRIN	

MS APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 29, 2004
(Monday)

Transmitted herewith is an Appeal Brief (in triplicate) on behalf of the Appellants in connection with the above-identified application.

A Notice of Appeal was filed on .

The fee has been calculated as shown below:

☐ Please charge Deposit Account No. 02-2448 in the amount of \$0.00. A triplicate copy of this sheet is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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(Rev. 02/08/2004)

PATENT
0020-4518P



IN THE U.S. PATENT AND TRADEMARK OFFICE

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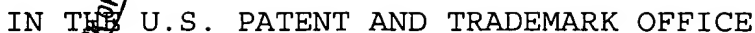


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BRIEF ON BEHALF OF APPELLANTS

MS APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

March 29, 2004

(Monday)

Sir:

This Appeal Brief is respectfully submitted on behalf of the Appellants in connection with the above-identified application.

This is an appeal from the Examiner's Final Office Action dated July 29, 2003 finally rejecting claims in connection with the present application. The appealed claims are presented in the attached Appendix.

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(1) REAL PARTY IN INTEREST

In accordance with 37 C.F.R. 1.192(c)(1), the real party in interest of the present application is the Assignee as recorded at Reel/Frame 9895/0198, which is TEIKOKU SEIYAKU CO., LTD. of Kagawa-ken, Japan.

(2) RELATED APPEALS AND INTERFERENCES

In accordance with 37 C.F.R. 1.192(c)(2), it is submitted there are no other appeals or interferences known to the appellants, the undersigned, or the Assignees which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) STATUS OF THE CLAIMS ON APPEAL

Claims 14, 16 and 23-25 are appealed from the Examiner's Final Office Action dated July 29, 2003, finally rejecting these claims. Claims 1-13, 15 and 17-22 have been cancelled. Claims 26 and 27 are withdrawn from consideration as being drawn to nonelected subject matter.

(4) STATUS OF AMENDMENTS

All Amendments have been entered into the Official Record.

(5) SUMMARY OF THE INVENTION

There are five separate embodiments of the present invention as follows:

[A] An ointment consisting of acetyl salicylic acid and a base selected from the group consisting of hydrocarbon gel, petrolatum and a mixture thereof without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein when the base is hydrocarbon gel or a mixture of hydrocarbon gel and petrolatum, the acetyl salicylic acid is in a range of 20 to 30% by weight per total weight, and wherein when the base is petrolatum, the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight; (support for this embodiment can be found in claim 3, as originally filed, page 6, lines 5-8 and page 3, line 15 of the specification);

[B] An ointment consisting of acetyl salicylic acid and a base selected from the group consisting of hydrocarbon gel, petrolatum and a mixture thereof without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein when the base is hydrocarbon gel or a mixture of hydrocarbon gel and petrolatum, the acetyl salicylic acid is in a range of 20 to 30% by weight per total weight, and wherein when

the base is petrolatum, the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight,

and wherein the ointment is an anhydrous ointment (support for this embodiment can be found in claim 3, as originally filed, page 6, lines 5-8 and page 3, line 15 of the specification);

[C] An ointment consisting of acetyl salicylic acid and a petrolatum base without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight (support for this embodiment can be found in claim 3, as originally filed, and page 6, lines 5-8 of the specification);

[D] An ointment consisting of acetyl salicylic acid and a petrolatum base without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight, and wherein the petrolatum is selected from the group consisting of white petrolatum and yellow petrolatum (support for this embodiment can be found in claim 3,

as originally filed, and page 3, line 15 of the specification);
and

[E] An ointment consisting of acetyl salicylic acid and a hydrocarbon gel base without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein the acetyl salicylic acid is in a range of 20 to 30% by weight per total weight (support for this embodiment can be found in claim 3, as originally filed, and page 6, lines 5-8 of the specification).

(6) ISSUES ON APPEAL

[1] The sole issue on appeal is whether claims 14, 16 and 23-25 are adequately described in the specification so as to comply with 35 U.S.C. § 112, first paragraph and thus whether the rejection for containing new matter is improper.

(7) GROUPING OF CLAIMS

It is respectfully submitted that the presently appealed claims 14, 16 and 23-25 should each be considered to stand and fall based on the following grouping: Group [III] contains claims 14 and 16; Group [I] contains claims 23-24; and Group [II] contains claim 25.

Appellants respectfully submit that the claims of Group [III], claims 14 and 16, should be grouped differently than the

claims of Group [I], claims 23-24, and the claim of Group [II], claim 25, since each of the groups require different considerations with regard to the presence of new matter. Claims 23-24 require the use of 25-30wt% acetyl salicylic acid (aspirin) in a petrolatum base, wherein the lower endpoint of the concentration range, 25wt%, finds written description support in an example in the specification at page 6, lines 5-8. This is in distinction to the invention described in claim 25 which requires the use of 20-30wt% acetyl salicylic acid in a hydrocarbon gel base wherein the lower endpoint of the concentration range, 20wt%, finds written description support in a range disclosed on page 3, line 15 of the specification. The invention of Group [III], claims 14 and 16, should be separately considered, since these claims contain the both the embodiments of Group [I] and Group [II] which are each separately considerable.

(8) **ARGUMENTS**

(i) Summary of Examiner's Arguments Regarding The Ranges

In support of the rejection of claims 14, 16 and 23-27 under 35 U.S.C. § 112, first paragraph, the Examiner states in the December 11, 2003 Advisory Action as follows:

The Examiner points out that nowhere in the application does not the specific range of 25-30% find support that applicant had this specific range in mind at the time of filing. The Examiner notes the lower limit of 25% and finds support for this lower limit; however, the range between 25-30% is not found. Further, not only as applicant amended the present weight range, the

applicant has amended the percent weight range in accordance to the carrier. This stipulation "wherein when the base is hydrocarbon gel or a mixture hydrocarbon range of 20 to 30% by weight per total weight, and wherein when the gel and petrolatum, the acetyl salicylic acid is in a base is petrolatum, the acetyl salicylic acid is 25 to 30% by weight per total weight" has no support in the application. (Emphasis in original).

(ii) Appellant's Arguments Supporting Patentability

In response to the above-reasons indicated for the rejection under 35 U.S.C. § 112, first paragraph, the following arguments are respectfully submitted in support of the patentability of each group of appealed claims.

Specifically, the Examiner has maintained the position that the concentration ranges of 25-30 wt.% and 20-30 wt.% as described in the last clause of claim 14, constitute new matter despite Appellant's assertion to the contrary.

For clarity, Appellant will now discuss each of these ranges individually.

(iii) Group I, claims 23 and 24, which recite 25-30wt% of Acetyl Salicylic Acid with a base of petrolatum:

Appellant respectfully submits that there is sufficient *implicit* support for the range of 25-30 wt. % by combining the range of 0.001-30 wt. % as disclosed on page 3, line 15 with the lower limit of 25 wt. % as would be found from the example given on page 6, lines 5-8 of the present specification.

Appellant respectfully submits that the current case law supports Appellant's position.

"The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'" (citation omitted). *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). The failure of the specification to specifically mention a limitation that later appears in the claim is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented. *All Dental ProdX v. Advantage Dental Prods. Inc.*, 309 F.3d 774, 64 USPQ 2d 1945 (Fed. Cir. 2002).

With respect to amending numerical range limitations, such as in the present case, the Examiner's analysis is faulted, since the Examiner's analysis did not take into account which ranges one skilled in the art would consider are inherently or **implicitly** supported by the discussion in the original disclosure.

In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), at issue was whether the claim limitation of "between 35% to 60%" by weight of coffee solids constituted "new matter."

The specification recited a range of 25% to 60% and exemplified processes using 36% and 50% solids.

The court concluded that,

[i]n the context of this invention, in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants' invention.... The PTO has done nothing more than argue lack of literal support, which is not enough.

Similarly, in *In re Blaser*, 194 USPQ 122 (CCPA 1977), the issue was whether the phrase "said share of said water in said mixture is from 1.2 to 1.6 mols" had support in a parent case U.S. Serial No. 159,159. If this range did not have support, it would be new matter to the application and claim 12 would not have the benefit of priority back to the filing date of the parent case. The court noted that in the parent application, there was a range with an upper limit of 1.6 mols which was expressly disclosed and examples 1-6 therein ranged from 1.2 to 1.5 mols. The court found that, "[a]s a factual matter, persons skilled in the art would consider processes employing 1.2 to 1.6 mols water as part of appellants' invention and would have been led by U.S. Serial No. 159,159 so to conclude."

In other words, it was not "new matter" to recite a concentration range using a concentration value found in one of the exemplified embodiments as an endpoint in the claimed range.

In the present case, the Examiner has done nothing more than to argue lack of literal support, which is not enough. *In re Lukach*, 169 USPQ at 796, (CCPA 1971), holds that for a proper rejection based on new matter, the Examiner not only has the burden of showing that the claimed invention is not literally described in the specification, but also the Examiner has the burden to give reasons why there is not implicit written description support.

Accordingly, the specification provides sufficient support for the range of 25-30 wt.% by combining the range of 0.001-30 wt.% as disclosed on page 3, line 15 with the lower limit of 25 wt.% as would be found from the example given on page 6, lines 5-8 of the present specification.

The Examiner further asserts that recitation of the range 25-30wt.% in combination with petrolatum as a base is new matter.

In the February 12, 2004 Advisory Action, the Examiner states as follows:

However, for arguendo sake, if the applicant were allowed this specific range [of 25-30 wt%], the Examiner points out that not only as applicant amended the percent weight range, the applicant has amended the percent weight range in accordance to the carrier. This stipulation "wherein when the base is hydrocarbon gel or a mixture hydrocarbon range of 20 to 30% by weight per total weight, and wherein when the gel and petrolatum, the acetyl salicylic acid is in a base is petrolatum, the acetyl salicylic acid is 25 to 30% by weight per total weight" does not have support in the application. The applicant has not submitted any arguments or support to the specific range with the specific carrier. Applicant has amended the range according to the carrier

to carve around the prior art without showing ample support that the applicant possessed the invention as claimed at the time of filing.

In response, Appellants respectfully submit that the clause asserted by the Examiner as being new matter is simply a proviso. The use of proviso language has long been a sanctioned tool for carving around prior art, see for example *In re Johnson*, 194 USPQ 187 (CCPA 1977).

If such a "hypertechnical application" of the written description requirement of §112 as set forth by the Examiner were permitted, future applicants would in all likelihood find themselves in the predicament reflected in the following observation, by Judge Learned Hand:

If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new "invention," only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. *It is impossible to imagine any public purpose which it could serve.* [Emphasis added.] *Engineering Development Laboratories v. Radio Corp. of America*, 68 USPQ 238, 241-242 (CA2 1946).

Appellants note that the present specification at page 3, lines 1-13, teaches the use of acetyl salicylic acid in an ointment wherein the base is substantially anhydrous. The possible

bases include hydrocarbon gel and/or petrolatum. It is an important aspect of the invention that, regardless of whether hydrocarbon gel and/or petrolatum are used, the base is anhydrous to minimize the degradation of the acetyl salicylic acid over time.

Appellants also note that the present specification at page 3, lines 14-23, teaches that acetyl salicylic acid should be used in a range 0.001-30 wt% in hydrocarbon gel and/or petrolatum. At above 30 wt%, the base will not effectively protect the acetyl salicylic acid from degradation. Also, below 0.001 wt%, the acetyl salicylic acid will not exhibit the pharmacological activities.

As mentioned above, there is sufficient support in the specification for acetyl salicylic acid to be in the range of 25 to 30% by weight. There is also sufficient support to recite that the base is petrolatum. Accordingly, the invention recited in inventive claims 23 and 24 does not contain new matter, and each of claims 23 and 24 is patentable.

(iv) Group II, claim 25, which recites 20-30wt% of Acetyl Salicylic Acid which is a hydrocarbon gel:

Appellant respectfully submits that there is similarly sufficient *implicit* support for the range of 20-30 wt.% as recited in claim 14, by combining the range of 0.001-30 wt.% with the

range of 0.01-20 wt.%, both of which are disclosed on page 3, line 15 of the present specification.

In *Blaser* at 126, the claims recited "heating the reaction blend ... obtained after completing of said mixing to 80° C to 200°C." The specification disclosed initially mixing the starting materials (at temperatures of up to 80°C) and then heating the reaction blend to temperatures between 60°C and 200°C. The court framed the issue as "whether the disclosed range of 60°C to 200°C in [the specification] supports the recitation of 80°C to 200°C in the claims on appeal."

Appellants in *Blaser* relied on the rationale of *In re Wertheim, supra*, as "clearly applicable here." Appellants urged that if a disclosure of 25-60% solids content taught those skilled in the art that 35-60% was part of the invention in *Wertheim*, although the latter range was not expressly mentioned therein, then appellants' disclosure of 60°C to 200°C in the specification coupled with the range of "up to 80°C" would likewise teach the claimed range of 80°C to 200°C as part of appellants' invention. The *Blaser* court agreed with appellants and found that the range of 80°C to 200°C was not new matter.

In the present case, the Examiner has done nothing more than to argue lack of literal support, which is not enough. As mentioned above, for a proper rejection based on new matter, the Examiner not only has the burden of showing that the claimed

invention is not literally described in the specification, but also the Examiner has the burden to give reasons why there is not implicit written description support, see *Lukach* at 796.

Indeed, based on the findings in *Blaser*, it is proper to find sufficient implicit support for the range of 20-30 wt.% by combining the range of 0.001-30 wt.% with the range of 0.01-20 wt.%, both of which are disclosed on page 3, line 15 of the present specification.

Also, it is proper to find sufficient support for the range of 25-30 wt.% by combining the range of 0.001-30 wt.% as disclosed on page 3, line 15 with the lower limit of 25 wt.% from the example given on page 6, lines 5-8 of the present specification.

(v) Group III, claims 14 and 16

The claims of Group III, i.e. claims 14 and 16, recite the concentration and base features of both Groups I and II as recited in the alternative. For the reasons discussed above regarding Group I and II, for the separately recited ranges, the claims of Group III are equally patentable.

Conclusion

If any questions remain regarding the above matters, please contact Appellant's representative, **Garth M. Dahlen, Ph.D., Esq.** (Registry #43,575), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Enclosures: Appendix A: Claims on Appeal

APPENDIX A

CLAIMS ON APPEAL

Claims 14, 16 and 23-27 are pending and claims 26 and 27 have been withdrawn from consideration as being drawn to nonelected subject matter. Claims 14, 16 and 23-25 are appealed and are as follows:

14. An ointment consisting of acetyl salicylic acid and a base selected from the group consisting of hydrocarbon gel, petrolatum and a mixture thereof without any other additive for said acetyl salicylic acid and wherein the ointment does not contain water for dissolving said acetyl salicylic acid,

wherein when the base is hydrocarbon gel or a mixture of hydrocarbon gel and petrolatum, the acetyl salicylic acid is in a range of 20 to 30% by weight per total weight, and wherein when the base is petrolatum, the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight.

16. The ointment of claim 14, wherein the ointment is an anhydrous ointment.

23. The ointment of claim 14, wherein the base is petrolatum.

24. The ointment of claim 23, wherein the petrolatum is selected from the group consisting of white petrolatum and yellow petrolatum.

25. The ointment of claim 14, wherein the base is hydrocarbon gel.